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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,244	04/23/2001	Y. Tom Tang	PF-0620 USN	3310

7590

07/15/2003

Incyte Genomics Inc  
Legal Department  
3160 Porter Drive  
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EXAMINER

MAYES, LAURIE A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 07/15/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/830,244

Applicant(s)

TANG ET AL

Examiner

Laurie Mayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group II in Paper No. 12 is acknowledged. The traversal is on the ground(s) that unity of invention exists. This is not found persuasive because unity of invention does not exist as an isolated polynucleotide that encodes a protein with immunogenic activity and comprises at least five contiguous amino acid residues of SEQ ID NO: 1 is known in the art (WO 9845436-A2). Thus the different groups of invention lack a common, novel inventive step. Further, nucleic acids are classified in class 536, subclass 23.1 and there are over 7,500 patents in that class alone while amino acid sequences similar to the present invention are classified in class 530, subclass 324 with over 2,500 patents in that class.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and searches required for each, restriction for examination purposes as indicated is proper. As claims 21, 22 and 31-44 are drawn to non-elected inventions, only claims 23-30 drawn to the elected group of nucleic acids and nucleic acid constructs are examined.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (p. 10, lines 4 and 8). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

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***Claim Objections***

Claims 23, 24 and 28 and claims 25-27 and 29-30 dependent thereon are objected to as being dependent on non-elected claims 21 and 22. Appropriate correction (e.g., claims should be rewritten in independent format) is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 and claims dependent thereto are dependent upon a claim to a different product. The claim should be rewritten in independent format.

Claims 25, 29 and 30, and claims 23-30 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language in claims 25 and 30 "comprising a polynucleotide sequence" and in claims 21, 22 and 29 "comprises an amino acid sequence" is indefinite as this could include a fragment of the entire sequence of SEQ ID NOS: 1 or 2 or could include the entire sequence of SEQ ID NOS: 1 or 2. The language does not specify that the polypeptide comprises an amino acid sequence identical to SEQ ID NOS: 1 or 2.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al. (WO 98/45436). Jacobs et al. teach an isolated polynucleotide that encodes a protein with immunogenic activity, absent evidence to the contrary, and comprises at least five contiguous

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amino acid residues of SEQ ID NO: 1 is known in the art (see SEQ ID NO: 484 and copy of attached sequence alignment). Thus all of the elements of claim 21 are taught by Jacobs et al. and this claim is anticipated under 35 U.S.C. 102(b).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ciardelli et al. (US 5,837,816) in view of Jacobs et al. Jacobs et al. teach an isolated polynucleotide that encodes a protein with immunogenic activity, absent evidence to the contrary, and comprises at least five contiguous amino acid residues of SEQ ID NO: 1 is known in the art (see SEQ ID NO: 484 and copy of attached sequence alignment). Jacobs et al. do not teach a recombinant polynucleotide, nucleic acid constructs, or a method of making the above-mentioned polypeptide.

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Ciardelli et al. teach a method of making recombinant proteins using a promoter sequence, host cells, and nucleic acid sequences (cols. 9 and 10). As recombinant methods of making a protein are known in the art as shown by Ciardelli et al., it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to use the nucleic acid sequence taught by Jacobs et al. with nucleic acid constructs to recombinantly produce the desired protein encoded by the nucleic acid sequence because recombinantly constructed proteins often may be produced more cheaply and in higher quantities and contain less impurities than purified proteins. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

### ***Conclusion***

**Claims 23-30 are rejected.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123

*L. Mayes*  
Laurie Mayes  
Patent Examiner  
Art Unit 1653  
July 10, 2003

*Christopher S. Low*

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